

IN THE SPECIFICATION:

Please substitute an amended paragraph [12] at page 3 as follows:

[12] Figure 4A is a side plan view of the physiological pacing lead according to the present invention.

Please substitute an amended paragraph [31] at page 5 as follows:

[31] Figure 1 is a schematic diagram of a right side of a heart having an anterior-lateral wall peeled back to present a portion of a heart's intrinsic conduction system and chambers of a right atrium 40 2 and a right ventricle 6. Pertinent elements of the heart's intrinsic conduction system, illustrated in Figure 1, include a sinoatrial (SA) node 1, an atrioventricular node 2A, a bundle of His 3, a right bundle branch 4, and Purkinje fibers 5. SA node 1 is shown at a junction between a superior vena cava 12 and right atrium (RA) 40 2. An electrical impulse starting at SA node 1 travels rapidly through RA 40 2 and a left atrium 8 (Figure 15) to AV node 2A. At AV node 2A, the impulse slows to create a delay before passing on through a bundle of His 3, which branches, in an interventricular septum 7, into a right bundle branch 4 and a left bundle branch 84 (Figure 15) and then, apically, into Purkinje fibers 5. Following the delay, the impulse travels rapidly throughout right ventricle (RV) 6 and a left ventricle (not shown). Flow of the electrical impulse described herein creates an orderly sequence of atrial and ventricular contraction and relaxation to efficiently pump blood through the heart. When a portion of the heart's intrinsic conduction system becomes damaged, efficient pumping is compromised. Typically, a patient, whose SA node 1 has become damaged, may have a pacemaker system implanted wherein lead electrodes are placed in an atrial appendage 15. The lead electrodes stimulate RA 40 2 downstream of damaged SA node 1 and the stimulating pulse travels on to AV node 2A, bundle of His 3, and Purkinje fibers 5 to restore physiological contraction of the heart. However, if a patient has a

damaged AV node 2A, pacing in atrial appendage 15 will not be effective, since it is upstream of a block caused by the damage. Typically, this patient may have a pacemaker system implanted wherein lead electrodes are placed in an RV apex 16. RV apex 16 has been an accepted site for electrode placement since it is relatively easy to engage a lead electrode at this site and pacing from this site has been proven safe and effective. More recently questions have been raised regarding long-term effects of pacing from RV apex 16, since conduction from this site does not spread as rapidly as, and is contrary in direction to natural conduction.

Please substitute an amended paragraph [47] at page 13 as follows:

[47] Figure 8A is a top plan view and Figure 8B is a side elevation view of a distal portion of a physiological pacing delivery system 80 according to a preferred embodiment of the present invention. Delivery system 80 includes physiological pacing lead 26 and piercing tool 70. Figure 8B illustrates an interface of electrode array 28 and fixation element 35 with piercing tip 73 and longitudinal recess 78. According to the present invention, distal piercing tip 73 extends a length 82 beyond a distal end 341 of tapered tip 34 that equals a longitudinal travel 81 between a distal end 481 of distal portion 48 of helical hook 46 and distal edge 44 of collar 45. Length 82 allows piercing tip 73 to bore deep enough into tissue for electrode array 28 to advance within the tissue as fixation element 35 is engaged into a surface of tissue, as further described below, in conjunction with Figure 10B. Longitudinal recess 78 allows distal portion 48 of helical hook 46 to exit from lumen 77 of shaft 71 and spiral about shaft 71 and lead body 32 since an inner diameter 410 (Figure 4D) of distal portion 48 is greater than an outer diameter 711 of shaft 71. Since distal portion 48 of helical hook 46 extends outward from lumen 77, diameter of lumen 77 only needs to be large enough, in a zone encompassing longitudinal recess 78, to accommodate an outer diameter of collar 45; as a result, shaft 71 may be slideably received

within a catheter, used to guide delivery system 80 to an implant site, having a smaller diameter than a diameter that would be required if lumen 77 had to accommodated an outer diameter 411 (Figure 4D) of helical hook 46.

Please substitute an amended paragraph [48] at page 14 as follows:

Figure 9A is a side plan view of a means for assembling delivery system 80. As illustrated in Figure 9B, proximal end 29 of physiological pacing lead 26 is inserted, according to arrow G, into lumen 77 of piercing tool 70, at a distal end 701 of piercing tool 70, resulting in delivery system 80 illustrated in Figures 8A-B

Please substitute an amended paragraph [50] at page 14 as follows:

Figures 10A-B are a two-stage schematic diagram, with partial section, of delivery system 80 piercing a section of endocardial tissue 104 having bundle of His zone 30 (between dashed lines). Figures 10A-B illustrate guide catheter 90 positioned with distal end 92 against an RA endocardial surface 102 over endocardial tissue 104 encompassing bundle of His zone 30. A lumen 100 of guide catheter 90 slideably receives delivery system 80. In a first stage illustrated in Figure 10A, arrow C defines the direction in which delivery system 80 is pushed to pierce surface 102 and penetrate His zone 30 with wedge 76 at distal end of piercing tool shaft 71. According to the present invention, delivery system 80 is fully inserted once distal portion 48 of helical hook 46 contacts surface 102, as illustrated in a second stage illustrated in Figure 10B. Arrow D defines a rotation of lead body 32, initiated at proximal end 29 (Figure 4A), in order to engage helical hook 46 with endocardial tissue 104; arrow E defines the travel of electrode array 28 as lead body 32 is rotated and helical hook 46 engages tissue 104. Length 81 is the longitudinal travel of helical hook, equal to length 82. Length 82, defining a gap between distal tip 76 and distal end 341 of tapered tip 34, allows piercing tip 73 to bore deep enough into tissue for

electrode array 28 to advance within the tissue as fixation element 35 is engaged into a surface of tissue. Collar 45 prevents over-insertion of electrode array by butting up against endocardial surface 102. Arrow FE defines a direction in which piercing tool shaft 71 and guide catheter 90 are pulled for removal. Figure 3 defines implanted electrode array 28 of physiological pacing lead 26 after piercing tool 70 and guide catheter 90 are removed. Once electrode array 28 is implanted, every combination of electrodes, including 36, 37, 38, 39, and any additional electrodes, implanted either in the heart or subcutaneously, are energized to determine a first pair best suited for sensing and a second pair best suited for pacing. A first pair of electrodes, including, for example, electrodes 38 and 39, is selected based on a crispness and cleanness of a desired sensed signal. Alternatively first pair of electrode best suited for sensing may be on another implanted electrode array. A second pair of electrodes, including, for example, a subcutaneous electrode (not shown) and electrode 39, is selected based on a lowest threshold required to effectively stimulate bundle of His zone 30.

Please substitute an amended paragraph [53] at page 16 as follows:

Figure 13A is a flow chart of a general method 1300 for implanting electrode array 28 of physiological pacing lead 26. Implanting method 1300 of the present invention, illustrated by Figure 13A, may be followed using any of the embodiments of delivery systems disclosed herein. Starting at a step 130, means used to obtain venous access are well known in the art, and include the Seldinger technique performed with a standard percutaneous introducer kit. A physiological pacing site is selected, step 131, by knowledge of cardiac conduction pathways and visualization of a patient's cardiac anatomy, and may include electrical mapping via guide catheter 90. (Reference Figure 9.) A bore is created in a heart wall at the physiological pacing site, step 132, by any one of the piercing tips of systems disclosed herein, including that of piercing tool 70,

that of piercing stylet 110, that of alternate piercing stylet 150, and that of physiological pacing lead 26. (~~Reference Figures 7-10, 11, and 12, respectively.~~) Electrode array 28 coupled to lead body 32 is advanced into the bore, step 133. Distal fixation element 35, coupled to lead body 32, is engaged, by rotation of lead body 32, to heart wall to complete an implant of electrode array 28, step 134. (~~Reference Figure 10.~~) Steps 135 – 138 result in a selection of first and second pair of electrodes, as described above in conjunction with Figure 10B, to be used for pacing therapy.

Please substitute an amended paragraph [58] at page 19 as follows:

[58] Figures 16A-B are plan views of distal portions of alternative pacing leads which may be used to practice methods of the present invention. Figure 16A illustrates a pacing lead 250 including a helical electrode 255 extending distally from a distal end 252; helical electrode 255 includes a piercing tip 251 facilitating insertion into zone 220 and a geometry of electrode 255 serves to anchor electrode 255 within zone 220. Helical electrode 255 may be fixed to distal end 252 such that the entire lead 250 must be rotated to insert electrode into zone 220 or electrode 255 may be extendable and retractable per arrows K into and out from distal end 252, via rotation of an inner drive shaft; both embodiments are well known to those skilled in the art. Selecting a depth of electrode 255 in zone 220 is particularly facilitated by the extendable-retractable embodiment. Figure 16B illustrates a pacing lead 260 including an alternate embodiment including a distal end having a harpoon-like geometry for anchoring of electrodes 262A-B within zone 220. Figure 16B further illustrates electrode 262A including a piercing tip 261 facilitating insertion of electrodes 262A-B and an anchoring tine 262 263 extending proximally from electrode 262A. According to this illustrated embodiment, after electrodes 262A-B are inserted into zone 220 to an appropriate depth, wherein the pacing criteria previously described are met, lead

260 is pulled back slightly per arrow L to deploy tine ~~262~~ 263 per arrow M. It should be noted that lead 26, along with any of the associated tools previously described, may also be used to practice methods of the present invention.